

Message Text

UNCLASSIFIED

PAGE 01 STATE 095098
ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 CU-04 MED-03 /030 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP:JFRY
DHEW/PHS/OASH/OIH: MKEFAUVER
CU/OPP:EHICKS(INFO)
ARA/CAR:JTHYDEN(INFO)

-----272309Z 019616 /22

P 272206Z APR 77
FM SECSTATE WASHDC
TO AMEMBASSY SAN SALVADOR PRIORITY
AMEMBASSY KINGSTON PRIORITY

UNCLAS STATE 095098

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, ES, JM

SUBJECT: DEFECTIVE MEDICAL DEVICE (RECALL T-084-7)

1. FDA ADVISES OF THE FOLLOWING DEVICE RECALL:

PRODUCT INVOLVED: HEATED HOSES, 5 FT. LONG, CONTAINING
STEEL WARMING WIRE AND A COPPER RETURN WIRE. POLYVINYL
CHLORIDE PLASTIC IS USED AS A CONNECTION BETWEEN PATIENT
AND VENTILATOR.

PRODUCT IDENTIFICATION:

A. BREATHING HOSES ARE USED WITH J.H. EMERSON VOLUME
VENTILATOR 3-PV, IMV VENTILATOR 3-MV, AND TEMPERATURE
SENSOR-CONTROLLER 97-T OR 3V-TC.

B. HOSE NUMBER 3MV-230W
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HOSE NUMBER 3V-TC-2

MANUFACTURER/RECALLING FIRM:

J. H. EMERSON COMPANY
22 COTTAGE PARK AVENUE
CAMBRIDGE, MASSACHUSETTS 02140

2. REASON FOR RECALL:

THE HOSES ARE WARMED BY A SMALL ELECTRIC CURRENT PASSING THROUGH THE REINFORCING WIRE. IN ONE CASE, DURING VENTILATOR TEST THE SOLDERED CONNECTION BETWEEN THE STEEL WIRE AND THE COPPER RETURN WIRE FAILED, PERMITTING A SPARK TO IGNITE THE PLASTIC INSULATION. NO INJURIES OR DEATHS HAVE OCCURRED. A NEW TYPE OF WARMING HOSE HAS BEEN DESIGNED WITH THE SOLDERED CONNECTIONS OUTSIDE OF THE AIRSTREAM. MANUFACTURER REQUESTED IMMEDIATE REMOVAL OF ANY HEATED HOSES IN USE OR IN STOCK TO BE REPLACED BY UNHEATED HOSE UNTIL REDESIGNED HOSE IS AVAILABLE. ALL HEATED HOSE WIRE TO BE RETURNED TO MANUFACTURER WHICH WILL BE REPLACED AT NO CHARGE BY EMERSON. NEW HOSES WILL BE IDENTIFIED BY DISTINCTIVE MARKING ON HOSE CUFF.

3. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL NOTICE DATED MARCH 4, 1977. ANY QUESTIONS CONSIGNEES MAY HAVE CONCERNING RECALL SHOULD BE DIRECTED TO EMERSON COMPANY.

4. CONSIGNEES AS FOLLOWS:

MARCELO J. WOLF Y CIA
CALLE ARCE NO. 1219
SAN SALVADOR, EL SALVADOR

UNITS NUMBERED - 7695, 7696
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ULTIMATE RECIPIENT
INSTITUTO SALVADORENO DEL SEGURO SOCIAL
SAN SALVADOR, EL SALVADOR

MEDITRON MEDICAL ELECTRONICS AND SUPPLIES LTD.
P O BOX 348
KINGSTON 6, JAMAICA
UNIT NUMBER 1626
VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 27-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE095098
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770147-0804
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770412/aaaaakhy.tel
Line Count: 107
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 783e3e9c-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 07-Feb-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2675008
Secure: OPEN
Status: NATIVE
Subject: DEFECTIVE MEDICAL DEVICE (RECALL T-084-7)
TAGS: OGEN, ETRD, EIND, TBIO, ES, JM
To: SAN SALVADOR KINGSTON
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/783e3e9c-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009